Remarks

First, applicants note with appreciation the indication of allowability of claim 8 if rewritten in independent form. The Examiner will note that claim 8 has been rewritten in independent form embodying the limitations of parent claim 7 and claim 1. Since claim 7 was a multiple dependent claim depending alternately from claim 1 or claim 2, a new claim 12 has been inserted which corresponds to original claim 2 but depends from claim 8. Claims 8 and 12 are, therefore, allowable.

Before proceeding with a discussion of the rejections, it is first pointed out that throughout the specification and claims, the word "potentiating" (or "potentiated") has been changed to "potentisating" (or "potentisated") in order to more clearly define the invention. As discussed in the specification, the instant invention is a homeopathic pharmaceutical product. As is explained on page 1 of the specification, the method comprises successive steps of dilution of a starting material, this being a substance derived from botanical, animal or mineral source, in a carrier. The carrier could be, for example, water or alcohol. As is common in homeopathic medicine, the dilution is 1:10 in each step based on the diluted result of the preceding step. Thus, after two steps the dilution of the starting material is 1:100, etc. Generally speaking, after n steps the dilution is $1:10^n$. The mathematical term for n in the German language is "Potenz" which can be translated as "exponent" or "to the power of" when taking only the mathematical meaning into account.

In the field of homeopathic medicine, n describes the degree of dilution. Here, the German term "Potenz" or the English term "potency" is used (see the attached copies of two internet documents: 1) "Homeopathic Medicine Potency or Dilution" taken from www.ritecare.com. 2. "Principles of Homeopathy", taken from Bringhealth.com.

In German, the process of successive steps of dilution is called "potenzieren". It appears that when the original German text was translated to English in preparing the instant application, this was translated as "potentiated" or "potentiating". This does not appear to be an accurate translation because it is more commonly used to mean the ability to enhance or improve the efficiency of another material. A better term would seem to be "diluted by potentisation" (see the second page of the Bringhealth.com publication).

Accordingly, the instant specification and claims have been amended to clarify that the claimed method is a method of potentisating, that is, homeopathic dilution, rather than potentiating which would connote enhancing properties of a product. It is respectfully submitted that this amendment does not introduce new matter because this corrects a translation error and makes the terminology consistent with the recognized terminology in the art.

The Examiner rejected claims 1, 2, and 4-11 under 35 U.S.C. § 112, 2nd paragraph, as being indefinite. With respect to claim 1, the Examiner considered the language "at least one of" to be indefinite even though this is commonly

accepted claim language which is equivalent to "and/or". Nevertheless, claim 1 has been amended to change the language to Markush group language. This ground of rejection is now, therefore, moot.

The Examiner said that claim 4 recites that the agent is added as "accompanying material" which the Examiner considers to be vague and indefinite. This claim has been amended to indicate that the amino acids are added as additives.

With respect to claims 6, 7, and 9-11, the Examiner questioned how amino acids could be added by alcohol, air, water, or lactose. In answer to this question, it is pointed out that the art with which the instant invention is concerned is homeopathic medicine. The Examiner's attention is directed to paragraphs [0009]-[0013] of the instant specification and to the two articles submitted herewith. Under the accepted theories of homeopathic medicine (which may not necessarily be accepted by the traditional medical establishment), the amino acids are present essentially as impurities derived from airborne or water-borne sources, for example. Thus, while, for example, water is not an amino acid, it can contain amino acids. Keeping in mind that this invention is related to the art of homeopathic medicine, it is respectfully submitted that the claim language is definite and is not vague. The Examiner is, therefore, respectfully requested to withdraw this rejection.

The Examiner rejected claims 1, 2, 4, 9 and 10 under 35 U.S.C. § 102(e) as being anticipated by Cheng. This rejection is respectfully traversed.

Cheng teaches a composition and method for increasing insulin activity, that is, potentiating the insulin activity. It has already been shown that the word "potentiating" originally appearing in the instant claims was erroneous and that the meaning was not meant to be increasing activity. With that in mind, the Cheng reference is not relevant.

The Examiner rejected claims 1, 2, and 4 under 35 U.S.C. § 102(a) as anticipated by Porro et al. This rejection is respectfully traversed.

It is respectfully submitted that the Porro et al. reference is not relevant for the same reason that the Cheng reference is not relevant. The Examiner rejected claims 1, 2, 4-7, 9 and 10 under 35 U.S.C. § 102 as anticipated by Ho et al. This rejection is respectfully traversed.

Ho et al. teach a method of making an extract from a particular fruit and then concentrating the extract. Eventually, it is dried. This is precisely the opposite of the serial dilutions of the instant invention. Accordingly, Ho et al. is irrelevant.

The Examiner rejected claims 1, 2, 4, 9 and 11 under 35 U.S.C. § 102(a) as anticipated by Scanlon et al. This rejection is respectfully traversed.

This reference is irrelevant for the same reason that the other references are irrelevant. It does not teach serial dilution or potentisating. The Examiner is respectfully requested to withdraw this rejection.

Since all the claims are clearly in condition for allowance and distinguish over the prior art, whether taken singly or in combination. An early Notice of Allowance is in order and the same is respectfully requested.

If there are any questions regarding this response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket # 010562.50345US).

Respectfully submitted,

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~~METHOD FOR PRODUCING A POTENTIATED~~

~~PHARMACEUTICAL PRODUCT~~

METHOD FOR PRODUCING A POTENTISATED PHARMACEUTICAL PRODUCT

The invention relates to a method for a producing ~~potentiated~~ a potentisated pharmaceutical product for use in man, animals or plants.

~~Potentiated~~ Potentisated pharmaceutical products are used, for example, in homeopathic and anthroposophic medicine. The production method according to the Homöopathischen Arzneibuch (HAB – Homeopathic Pharmacopoeia) comprises the processes of diluting and subsequently shaking (in the case of liquids) or of triturating (in the case of solids). These processes are referred to collectively (that is, diluting plus shaking or diluting plus triturating) as ~~potentiating~~ potentisating .

At the same time, a portion of the starting material, for example, 9 parts of the ~~potentiating~~ potentisating medium (the carrier substance) are shaken or triturated (~~potentiated~~ potentisated). Usually, the diluting steps are 1 : 10 (D potency) and the 1 :100 and (C potency). Physicians, who use homeopathic pharmaceutical products, have confirmed that especially pharmaceutical products of the potency step D30

(corresponding to a dilution of 1 : 10^{30}) and higher (for example, D200) are also effective. Moreover, the carrier substance mathematically no longer contains a molecule of the starting substance, since the order of magnitude of Avogadro's number (6.023 x 10^{23}) was exceeded at step D24 (or corresponding to C12). However, the effectiveness, which nevertheless occurs, was explained in the literature by stating that "information" is transferred from the starting substance to the carrier substance. The nature of this information or how it is stored is not known.

Scientifically, the treatment with ~~potentiated~~ potentisated drugs is controversial, since there are no generally accepted theoretical explanations for it. Furthermore, no principle of action is known, which is compatible with known physiology and biochemistry. However, since the discovery of the ~~potentiating~~ potentisating principle more than 200 years ago, physicians and patients have time and again confirmed the therapeutic effectiveness of ~~potentiated~~ potentisated pharmaceutical products (also as veterinary medicines) and this form of pharmaceutical product and treatment has held up until now, in spite of the explanation predicament.

The preparation of appropriate pharmaceutical products is specified in the Homöopathischen Arzneibuch (HAB – Homeopathic Pharmacopoeia). As carrier substance (~~potentiating~~ potentisating

medium) for ~~potentiated~~ potentisated pharmaceutical products, water, alcohol (ethyl alcohol) and lactose are usually employed. Liquid pharmaceutical products are ~~potentiated~~ potentisated with alcohol or water, depending on the specification.

Until now, effectiveness studies with ~~potentiated~~ potentisated pharmaceutical products have not produced unambiguous results. Some studies have confirmed that the effectiveness, in comparison with a placebo, is increased. Other studies were unable to find an effect, which differed significantly from that of a placebo.

It can be concluded from this that manufacturers of such pharmaceutical products do not completely know the prerequisites for good effectiveness and attain these prerequisites only more or less by chance. It furthermore follows from this that the specifications of the HAB also do not completely include the prerequisites, which are necessary for attaining effectiveness.

The background for the, if anything, coincidental success is the fact that previously, it was not known how the carrier substance (the ~~potentiating~~ potentisating medium) takes over and stores the information of the starting substance and how the effectiveness of such types of ~~potentiated~~ potentisated pharmaceutical products comes about.

Natural water and tap water always contain traces of bound amino acids (proteinic materials) and free amino acids. When transferring the ~~potentiating~~ potentisating medium in air, additional small amounts of air-borne free and bound amino acids are taken up by the ~~potentiating~~ potentisating medium, as we have discovered in appropriate investigations.

Alcohol is produced by the fermentation of wine or fruit and the subsequent distillation to brandy or fruit liquor. The object of the distillation is to separate the aqueous portion from the alcoholic portion and to separate hazardous portions (such as a methyl alcohol) from the consumable alcohol. Aside from ethyl alcohol and (ethanol), further materials, such as other alcohols, aldehydes, esters and volatile proteins, amino acids, glycoproteins, lipoproteins, glycosides and lipids can additionally go over into the distillate. These additional materials are of decisive importance for the effectiveness of ~~potentiated~~ potentisated pharmaceutical products. This was previously not known. For this reason, varieties of alcohol are used, which contain these materials only in slight amounts, if at all.

The present production methods place great emphasis on the purity of the materials used for the production of pharmaceutical

materials. A portion of the product quality is seen to lie therein. This may be a further reason for using alcohol qualities without the accompanying materials named above. However, the suitability for effective ~~potentiated~~ potentisated pharmaceutical materials is decreased further unwittingly as the degree of "purification" is increased.

Attention is paid to purity also in the case of water. For example, water is purified particularly by multiple distillations, complete desalination, ultrafiltration, reverse osmosis and irradiation with ultraviolet light (as individual methods or in combination) or, if sufficiently pure water is already available, the latter is checked at least for its purity. By producing the ~~potentiated~~ potentisated pharmaceutical products under clean room conditions, the proportion of air-borne bound and free amino acids in the air is also reduced. Correspondingly fewer such acids can go over into the ~~potentiating~~ potentisating medium.

The effects of present methods of manufacturing ~~potentiated~~ potentisated pharmaceutical products and their raw materials in the direction of reducing their effectiveness as above are additive. However, this is hardly noticeable, since the measures are not all encountered simultaneously and suddenly and, instead, one measure after the other was introduced and introduced increasingly in the course of years and decades. Since it is so far not possible to check the effectiveness of

~~potentiated~~ potentisated pharmaceutical products, the abating effect is also unobserved in therapeutic practice. Admittedly, such decreases are suspected time and again by practitioners. However, it is hardly possible to check them.

It is an object of the invention to develop a method for the production of a ~~potentiated~~ potentisated pharmaceutical produce, by means which the effectiveness of the ~~potentiated~~ potentisated product is increased significantly in comparison with that of the ~~potentiated~~ potentisated pharmaceutical products used at the present time.

Pursuant to the invention, this objective is accomplished owing to the fact that a ~~potentiating~~ potentisating medium is used, which contains more than 400 nmoles/L of bound amino acid and/or 200 nmoles/L of free amino acids, that is, its content of amino acids is higher than that of ~~potentiated~~ potentisated media used at the present time.

This solution of the problem is based on an abandonment of the previous practice for the production of ~~potentiated~~ potentisated media. The scientific literature was searched for manufacturing conditions for homeopathic preparations, for which effectiveness studies (in groups of patients or in animal trials) provide the result of "no detectable effectiveness." In such cases, it was frequently noted that doubly-distilled

water or particularly pure alcohol was used as ~~potentiating~~ potentisating medium.

In addition to experience and an evaluation of the literature, there is a further justification for our measures to increase the effectiveness of ~~potentiated~~ potentisated pharmaceutical products. This justification is a new theoretical concept of how ~~potentiated~~ potentisated pharmaceutical products store the information and how they could act. This theoretical concept follows on from known biochemical and physiological knowledge and finally also helps to understand the mode of action of ~~potentiated~~ potentisated pharmaceutical products.

Upon diluting and shaking or triturating (which can be regarded physically as a stimulating process), the electromagnetic structure of the molecules of the starting substance spreads out in their molecular environment. This acts on the proteinic substances and amino acids, contained in the ~~potentiating~~ potentisating medium, and converts these into an image of the starting substances. It is thus assumed that the amino acids and peptide molecules, which are particularly mobile in the aqueous medium, are rearranged under the influence of the molecules of the starting substance. Presumably they assume a structure, which simulates the structure of the starting substance (the pharmaceutical product, which is to be ~~potentiated~~ potentisated). Graphically, this can be

envisioned to be similar to the production of a plaster impression (negative shape). In the next step, the plaster impression is filled up once again and a positive reproduction of the original is formed. In the next step, a negative impression is formed once again from this reproduction and on and so forth. A change in the action, corresponding to the positive and negative shapes, has actually been described in laboratory experiments in literature. However, to what this change may be attributed, was also not explained here.

The described passing on of structure can be regarded as the material basis of the transfer of information postulated in the literature.

The ~~potentiating~~ potentisating process can therefore consist therein that the disordered amounts of proteinic materials, contained in the ~~potentiating~~ potentisating medium, change their structure and, under the influence of the starting substance, which is present predominantly in an ordered manner, change over into a configuration similar to that of the starting substance. In the next ~~potentiating~~ potentisating step also, a similar process can be imagined once again. Around the ordered, proteinic materials, a common field is formed, which is stronger than the proteinic substances of the ~~potentiating~~ potentisating medium, which admittedly are numerically more numerous, yet, because of their diversity, are not

capable of a successful order. Upon shaking, the ordered minority imposes its order (structure, configuration) and impresses it on the other.

A similar change is known in biochemistry as the gene-antigen principle. Anti-antigens for the antigen are also known. This principle of the biochemical passing on of similitude can already also theoretically suggest that proteinic materials can participate in the ~~potentiating~~ potentisating process.

The passing on of structure may be possible, because proteinic materials are chain molecules or molecular complexes, which are present in water or alcohol as a movable structure. This structure is stabilized by hydrogen bonding. However, upon appropriate electromagnetic stimulation, such as that, which necessarily occurs during shaking in dipolar liquids, such as water and alcohol, these hydrogen bonds can be transformed. A similar process can be ~~imagines~~ imagined in the case of proteinic substances and amino acids in lactose, only that the solid body cluster structures, which have become known in the last fifteen years, must be called upon here. Solid body clusters are structures between molecular structures and crystalline structures. They are ordered, but are not as immovable as solid molecules or crystals and, instead, are more prone to rearrange.

Polyamino acids are typical molecular complexes of the type under consideration here. They are known as peptides, proteins, enzymes, hormones, ovalbumins, albumins, etc. However, sugars are also suitable for forming complicated structures and are known as polysaccharides. This is all the more so if additional bonds to peptides are present (glycoproteins). Likewise, fatty and oily compounds (lipids) are capable of forming chains, again particularly in conjunction with peptides (lipoproteins).

Further possible molecular complexes of the type in question here are loose interlinkages of free amino acids. Amino acids are molecules with an acidic and a basic end. In proteins, there is a stable bond (covalent bond or peptide bond). Without peptide bonding, a loose attraction between basic and acidic ends of different amino acids is possible. This is a low-energy bond, similar to hydrogen bonding between different water molecules. Amino acids exist in great diversity; more than 300 types are known.

They can also be a weak attraction between sugar molecules, with the formation of microstructures. The cluster structures of solids are described in the literature. In the case often lactose, the participation of proteins and/or of amino acids is also regarded as decisive pursuant to the

invention. However, they are represented differently, depending on the synthesis employed for the lactose.

The actual carrier of the information storage in ~~potentiated~~ potentisated pharmaceutical products, which has previously not been explained, is seen to lie in said structure-forming substances. The class of proteinic substances just happens to be the central substance group of biochemistry. Proteinic substances, such as enzymes, hormones, peptides, etc. participate in the majority of physiological reactions. This means that one may suspect that the ~~potentiated~~ potentisated pharmaceutical products also act in this manner. Owing to the fact that, as it were, a unilateral single substance (the starting substance) impresses its configuration in a plurality of other proteinic substances, one can imagine that this substance is more flexible in reaching all organs in man or animals, so that they can be more effective, without showing the one-sidedness of a particular chemical effect. This makes the effectiveness as well as the lack of side effects plausible.

The invention is based on the realization that the previously unknown active ingredient portions are located especially in the so-called "impurities" of water and alcohol and lactose. The invention therefore consists of using water, alcohols and lactose, which contain proteinogenic and physiological, free amino acids and/or proteinic material (bound amino

acids) as a component of ~~potentiated~~ potentisated pharmaceutical products or such materials are added to them for increasing the effectiveness.

The ~~potentiated~~ potentisated preparation, produced according to the inventive method, can also be used for being sprayed on lactose in tablet, spherical or other form or mixed or trituated therewith, in order to produce a ~~potentiated~~ potentisated pharmaceutical product with a different form of administration. It is particularly advantageous for the present invention if, as ~~potentiating~~ potentisating medium, an alcohol is used, which is obtained by fomenting plants, which, on the one hand, have a particularly high content of free and bound amino acids in the alcohol (such as blackthorn). Provisions can also be made when water is used as ~~potentiating~~ potentisating medium, so that the free and bound amino acids initially are taken from an alcohol and then added to the water.